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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,735	12/27/2000	Bernd Dorken	028622/0102	3749
22428	7590	09/27/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			HELMs, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/673,735

Applicant(s)

DORKEN ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16, 20-23, 30, 33 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 20-23, 30, 33 and 35-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 2, 3-4, 21, 30, 37, 40-41 have been amended.  
Claims 17-19, 24-29, 31-32, 34 have been canceled.  
Claims 44-45 have been added.
2. Claims 1-16, 20-23, 30, 33, 35-45 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains NEW GROUNDS of rejections.

#### ***Rejections Withdrawn***

5. The rejection of claims 1-4, 21-23, 30, 33, 35-38, 40-43 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims and arguments.

#### ***Response to Arguments***

6. The rejection of claim 11 and newly added claim 44-45 under 35 USC 112, first paragraph is maintained.

The response filed 7/20/04 has been carefully considered but is deemed not to be persuasive. The response states that support for "at least one CDR" or at least two or three can be found in the specification and in support of the position that not all CDRs are necessary, the response cites Olsen and Sompuram as support (see pages 11-12 of response). In response to this argument, while it is known that some and maybe not all CDRs are needed for contacting antigen, as stated in Rudikoff the CDRs are in the context of structural requirements and even though one may not contact antigen it is still needed in its structural role for the other CDR contacting residues. In addition, the molecule of Olsen is stated to be "unique" and as such it would not be represented of immunoglobulins in general. In fact removal of the light chain in the molecule and still retain some function is not standard in immunoglobulins and in addition the present molecule has not been demonstrated to have this "unique" property. With regard to the Sompuram paper again the example is not representative of immunoglobulins in general and in addition the paper points to the CDRs as a structural features that are needed to stabilize other parts of the molecule (see page 1079). Therefore, the reference teaches that loss in binding results in structural distortions imposed by poly-glycine replaced CDRs (see page 1079). Therefore, one skill in the art would not expect antibodies as claimed which do not have a full set of CDRs to bind antigen.

7. The rejection of claims 1-16, 20-23, 30, 33, 35-43 and newly added claims 44-45 under 35 USC 103(a) as being unpatentable over Bohlen et al and further in view of Mack et al and as evidenced from the specification and Blattler et al is maintained.

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The response filed 7/20/04 has been carefully considered but is deemed not to be persuasive. The response states that the bispecific antibody of Bohlen was produced by hybrid-hybridoma technology and T cell stimulation could only be achieved by combination of the bispecific antibody and anti-CD28 antibody (see page 12-13 of response). In response to this argument, it is immaterial that the bispecific was made by hybrid-hybridoma techniques. The art teaches a bispecific antibody that binds CD19 and CD3 as required in the claims and in combination with Mack (who teaches obtaining the DNA encoding for light and heavy chains) one would make a single chain antibody for the reasons given in the rejection. In addition, it is also immaterial that the anti-CD28 antibody was needed because the product claims do have anything to do with this and the method claims for treatment, claim 30 for example, comprises administration which means other steps could be performed. The response states that the CD19XCD3 antibody of the invention has unexpected properties and the antibodies in the prior art needed 100ng/ml for reduction of the number of CD19 positive cells and the present invention needs 0.1 to 1 ng/ml (see page 14 of response). In response to this argument, the unexpected properties are not commensurate in scope with the claims because the claims are not limited to the antibodies with the unexpected properties (those with all CDRS defined in SEQ ID NO:9).

### ***Conclusion***

8. No claim is allowed.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,

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1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER